IN THE DRAWINGS:

Each of Figures 1, 2, 3, 7 and 8 has been amended as shown on the Replacement Sheets attached hereto.

R E M A R K S:

The present Amendment makes editorial changes in the title, specification, drawings and claims, and adds an abstract, to conform the present PCT application to the requirements of United States patent practice.

5   The cancellation of claims 1-19 in favor of claims 20-37 presented herein has been done solely because the amount of line throughs and underlining that would have been necessary to conform original claims 1-19 to the requirements of United States patent practice would have been unduly burdensome and confusing.   No change in the claim language between

10   original claims 1-19 and claims 20-37 has been made for the purpose of distinguishing any of those claims over the teachings of the prior art of record. Accordingly, no change in the claim language between claims 1-19 and claims 20-37 is intended by the Applicants as a surrender of any of the subject matter encompassed within the scope of original claims 1-19.

15   Early consideration of the application on the merits is respectfully requested.

Submitted by,

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~~Method and apparatus for filtering out an EMG-signal~~

~~Description~~

~~The present invention is directed to a method according to the preamble to claim 1, device according to the preamble to claim 7 and a computer program product according to the preamble to claim 13.~~

SPECIFICATION

TITLE

METHOD, DEVICE AND COMPUTER PROGRAM PRODUCT FOR FILTERING AN EMG SIGNAL OUT OF A RAW SIGNAL

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention concerns a method, device and computer program product for the purpose of filtering an EMG signal out of a raw signal, i.e., for extracting an EMG signal from a raw signal that contains the EMG signal, among other signal components.

Description of the Prior Art

Sensing of EMG-signals in a patient's diaphragm by placing a catheter with a number of electrodes in esophagus is a known technique, which is described in, among others, ~~US~~ United States Patent No. 5,671,752. The EMG-signals received can be used in connection with mechanical ventilation of patients, which among others is described in ~~US~~ United States Patent No. 5, 820,560 and WO 98/48877.

Sensing of EMG-signals from the diaphragm can even take place outside the body with electrodes placed on the patient, such as described in e.g. ~~US~~ United States Patent No. 4,248,240.

If a catheter with electrodes is guided down in the esophagus the electrodes lie on both sides of the diaphragm and at different distances therefrom. Each electrode's position relative to the diaphragm is normally not known and furthermore can vary when the patient breathes or moves in another way.

Since the EMG-signal from the diaphragm is relatively weak, in particular compared to interferences from EKG, a continuous desire is to in the best way attain the highest quality possible signal handling of the raw signal which the sensors detect. This is evident even in WO 01/03579. In WO 01/03579 it is assumed that the electrodes' location in relation to the center of the diaphragm is known. Then the electrodes are weighted based on location and symmetry, in which the EKG signal is taken into account in a traditional way.

~~Previously known~~ Known methods for compensating for the EKG signal include, among others, using a band pass filter which filters out the frequencies where the EKG signal normally appears. It is also known to measure the EKG signal separately and then remove an equivalent signal from the measured EMG signal.

None of these methods ~~consider~~ takes into account the actual disturbance the EKG signal creates in a particular measuring situation in a particular patient. This disturbance also varies with time.

The known methods also fail to consider that the electrodes location relative to the diaphragm often varies during a single measurement.

SUMMARY OF THE INVENTION

~~It is a goal~~ An object of the present invention is to provide a method and a device and a computer program product for measuring EMG signals ~~which takes~~ that take into consideration that the electrodes location varies during a measurement.

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~~This goal is achieved in accordance with the invention by the method above including the characteristics in the characterizing part of the independent claim 1 and the device above including the characteristics in the characterizing part of the independent claim 6. The goal is also achieved with a computer program product comprising the elements in the characterized part of the independent claim 10.~~

~~Advantageous designs and further developments of the method are evident from the independent claims.~~

<u>The above object is achieved in accordance with the present invention by a method, device and a computer program product (i.e., a computer-readable medium encoded with computer program data) wherein a raw signal is obtained from a number of electrodes that are adapted for placement in a patient to capture signals from the patient's diaphragm, each electrode having an associated signal channel, wherein a signal-to-noise ratio is determined for each signal channel and a weighting factor is generated for each signal channel based on the signal-to-noise ratio, and the channels are summed dependent on the weighting factors.</u>

By selectively estimating the signal-to-noise ratio for each signal channel and arranging significance factors depending upon the signal-to-noise ratio, the channels with the highest quality can be used more effectively for determining the EMG-signal.

Since EKG-signals constitute a ~~main~~ <u>primary</u> disturbance source, the determination can in large part be done in relation to these signals. The signal-to-noise ratio can then be determined as the quotient between an estimated EKG-activity and an estimated EMG-activity. The quotient can be determined so that a high estimated EMG-activity is always awarded, e.g. by applying the equation

$$\frac{R^2}{R+S}$$

where R represents the EMG-activity and S represents the EKG-activity.

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BRIEF DESCRIPTION OF THE DRAWINGS

~~An example of the method and the device according to the invention is described in connection with the figures. In this connection, there is shown in:~~

Fig. 1 <u>shows</u> a device according to the invention connected to a patient who is undergoing respiratory therapy[,]<u>.</u>

Fig. 2 <u>shows</u> a first example of electrode coupling for receiving a raw signal[,]<u>.</u>

Fig. 3 <u>shows</u> a second example of electrode couplings for receiving a raw signal[,]<u>.</u>

Fig. 4 <u>is</u> a flowchart describing the steps ~~which~~ <u>that</u> are included in the signal treatment with the method according to the invention[,]<u>.</u>

Fig. 5 <u>is</u> a flowchart showing how an ECG-activity is estimated with the method according to the invention[,]<u>.</u>

Fig. 6 <u>is</u> a flowchart showing how an EMG-activity is estimated with the method according to the invention~~, and~~ <u>.</u>

Fig. 7 and Fig. 8 <u>are</u> flowcharts ~~which show how~~ <u>showing,</u> respectively<u>,</u> <u>how</u> an ECG activity and an EMG activity are estimated according to the method according to an alternative embodiment ~~of the invention~~<u>.</u>

Fig. 9 <u>is</u> a flowchart showing how a weighing of signals on different signal channels can be obtained with the method according to the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

<u>The</u> ~~To clarify, the concept of~~ signal and raw signal are defined to ~~comprise~~ <u>encompass</u> n-1 signals from the n electrodes/sensors, and ~~to~~ <u>for</u> the n-1 signals there are n-1 channels.

Fig. 1 shows a device 2 for filtering and analysis of EMG-signals according to the invention. The device 2 can in a known way be connected to a patient 4 via a catheter 6 with a number of electrodes 8A, 8B, 8C, 8D in one end (four electrodes are shown, but the number can be larger or smaller). By

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placing the catheter 6 in the esophagus (gullet) of the patient 4, the electrodes 8A, 8B, 8C, 8D can be placed in different locations in the diaphragm 10 (the size of which has been exaggerated in the figure Fig. 1 to indicate the relative placement of the electrodes 8A, 8B, 8C, 8D). In an analysis unit 12 in the device 2, filtering and analysis of the raw signal from the catheter 6 is done to extract the highest quality EMG-signal possible.

In this connection, the raw signal can be received in many different ways. Figs. 2 and 3 show two ways embodiments. From Fig. 2 it is evident that the electrodes 8A, 8B, 8C, 8D are coupled together in pairs via three couplers 14A, 14B, 14C and in that way give rise to a three-channel raw signal (with e.g. nine electrodes, eight channels are received).

In Fig. 3 an example is shown where the respective electrodes 8A, 8B, 8C, 8D are connected to a reference electrode 16 (which e.g. can be grounded) via four couplers 14D, 14E, 14F, 14G. This gives rise to results in a four-channel raw signal (for eight channels in this arrangement, eight electrodes and one reference are required).

Naturally an arbitrary number of electrodes, be used and for n electrodes n-1 signals are allowed, and thereby n-1 channels.

More information regarding the catheter, the sensors and the entire process to capture raw signals from the diaphragm via esophagus can be found in e.g. US United States Patent No. 5,671,752 and WO 01/03579. As already noted, electrodes connected outside the body can even be used instead of completely non-invasive receiving of EMG-signals.

The patient 4 can also be connected in conventional ways to a ventilator system 18, which in turn can be connected to the device 2. The respiratory therapy given via the ventilator system 18 in that way can be influenced by the EMG-signal, which is extracted from the raw signal from the diaphragm 10. This influence can be done in many different ways, of which some are described in US United States Patent No. 5,820,560 and WO 99/43374.

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The present invention is directed to the device 2 and, to be precise, the analysis unit 12. The analysis unit 12 filters EMG-signals out of the raw signal from the catheter 6. <u>The analysis unit can be operated by a computer program encoded on a computer-readable medium, such as a CD-ROM 13.</u> In that connection a number of signal channels are used, as noted above.

To receive the highest quality possible in the EMG-signals, the raw signal contains in addition to EMG even EKG, alternating current noise, noise, movement ~~artefacts~~ <u>artifacts</u> and other low frequency disturbances, filtering in the analysis unit 12 is done according to the method described below, which can be performed <u>in an</u> analog[[,]] <u>or</u> digital <u>manner,</u> or as a combination ~~of these~~ <u>thereof</u> and <u>can</u> be realized in hardware, software or in a combination ~~of these~~ <u>thereof</u>.

The method is described in connection with the flowcharts in Figs. 4, 5, 6, 7, 8 and 9.

Fig. 4 shows a flowchart which describes the overall signal handling in the analysis unit 12. The general handling is as follows.

The raw signals from the sensors are input by a (multi-channel) input 22 and first pass a first high pass filter 24. The purpose of this is to filter away movement artifacts and other low-frequency interferences. The breaking frequency should be lower than 10 Hz.

In the next step, the signals are filtered in a non-linear low pass filter 26. The purpose of this is to smooth the signal when it has a high amplitude, which typically happens with the existence of EKG-signals. The breaking frequency should lie within an interval of about 50-700 Hz. Where in the interval the breaking frequency lies depends on the energy or the amplitude of the signal. Higher amplitude results in lower breaking frequency. The non-linear low pass filter 26 should even have a dynamic component, namely that the breaking frequency changes with a time constant.

Subsequently, the signals pass a second high pass filter 28. The purpose of the second high pass filter 28 is to select the frequency interval

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where the EMG-signal lies. The breaking frequency is therefore chosen to the lower regions of the bandwidth of the EMG-signal which is about 100 Hz.

The block 26 and 28 can be replaced with an adaptive band pass filter which is described in our parallel application 0303061-6, in connection to figure 6 in that application.

In the next step, nearby channels are differentiated from each other in a differentiator 30. The purpose of this is to remove ringing in the filter and is based on the assumption that nearby channels are correlated with reference to common-mode interferences.

Subsequently, the energy content of the signal is determined in an RMS-former 32 (Root Mean Square). To reduce any remaining spikes in EKG-signals (foremost related to the QRS-complex in the EKG-signal), the derivative of the signal from the RMS-former 32 is limited in a rate limit block 34.

In the next step, a summation is done in a ~~summator~~ summing unit 36. The purpose of the ~~summator~~ summing unit 36 is to weigh together the channels. This is done by multiplying the signals in the respective channels by a weight factor (see below), summing and normalizing the signals. In this connection the ~~weight~~ weighting factor can be squared to more selectively promote the channels with good signal-to-noise ratio. In principle, the ~~summator~~ summing unit 36 can be seen as a channel selector ~~where~~ in which the channels ~~which~~ that have the highest ~~weight~~ weighting factor are ~~chosen~~ cut out while the channels with poorer SNR can be allocated the value 0 in extreme cases.

The ~~weight~~ weighting factor for the respective channels is determined as follows.

After the first high pass filter 24, the signals in the channels are also passed to an EKG-detector 38. The purpose of the EKG-detector 38 is to establish the presence of the EKG-signals in the channels. If a single channel indicates the presence of an EKG-signal, an estimated EKG-activity is

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calculated for all of the channels. The determination of the estimated EKG-activity is done in a first calculation block 40. The output signal from the EKG-detector 38 is ~~even led~~ supplied to a second calculation block 42. ~~More on these below.~~

In ~~a corresponding way as~~ the manner described above, the presence of EMG-signals can also be established. This is done in an EMG-detector 44, which is fed with the signal from the second high pass filter 28.

The output signals from the EMG-detector 44 are led to the second calculation block 42.

In addition to the signals mentioned above, the first calculation block 40 and the second calculation block 42 have a further input signal, namely the signal after the rate limit block 34

The EKG detector 38 and the EMG detector 44 can be designed in different ways. In one formulation the EKG detector 38 is designed to, for each channel, that is, for each signal which is received from an electrode to detect if the EKG signal exceeds a limit value which is defined for the EKG signals. To make this comparison the raw signal is filtered in a band pass filter to take away the relevant frequency band for an EKG signal and the output signal from the band pass filter is compared with the set threshold. If the output signal is higher than the threshold the EKG signal is considered present.

In an alternative embodiment both the detectors 38, 44 are designed so that a first probability function P_{EKG} is determined for each channel. P_{EKG} ~~reflects~~ indicates the probability that an EKG signal is present in the signal. A second probability function $P_{EMG} = 1 - P_{EKG}$ ~~reflects~~ indicates the probability that an EMG signal is present in the signal.

The probability functions are calculated from a frequency analysis for the respective EKG and EMG signals.

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The function of the first calculation block 40 is evident from Fig. 5. The signal from the EKG-detector 38 goes into a first decision block 46. Here it is established whether an EKG-signal is present in one of the channels (output yes) or not (output no). If there is no EKG-activity, the activity level is set to 0 in block 48 (estimated EKG-activity = 0). If an EKG-signal is present in one of the channels, the estimated EKG-activity S is calculated for all the channels, which is done via a low pass filter 50, which also receives the filtered signal from the rate limit block 34. In the low pass filter 50, the D.C. tension level for each channel is in principle determined, the filtered signal from rate limit block 34, (a breaking frequency of a few Hz can be accepted), which in that connection represents the estimated EKG-activity S.

The function of the second calculation block 42 is ~~evident from~~ <u>explained in</u> Fig. 6. The signal from the EKG-detector 38 goes into a second decision block 52. If an EKG-signal exists (output yes), the estimated EMG-activity is set to 0 in block 54. If no EKG-signal exists (output no), it is investigated whether there exists some EMG-signal (from the EMG-detector 44) in a third decision block 56. If no EMG-signal exists (output no), the activity is set to 0 in the block 54. If there exist EMG-signals, the estimated EMG-activity R is calculated by passing the signal, the filtered signal from Rate limit block 34, through a low pass filter 58.

Another embodiment of the blocks 40 and 42 are shown in ~~figures~~ <u>Figures</u> 7 and 8, respectively.

Figure 7 shows an alternative embodiment of the first calculation block 40 for estimating the EKG signal. From the rate limit block 34 a low pass filter 50 in the first calculation block 40 receives the filtered raw signal. From the EKG detector 38 it receives as previously the estimation of the presence of EKG signal. In contrast to the above-described embodiment the value which is received from the EKG detector is a probability function P_{ECG} with a value between 0 and 1. The output signal from the calculation block 40 is an estimation of the effect contents in the EKG signal, which depends on the probability function.

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Figure 8 shows an alternative embodiment of the second calculation block 42 for estimating the EMG signal. The output signal from the EKG detector 38, P_{ECG} is ~~even~~ fed to a second calculation block 42 where the probability $1 - P_{ECG}$ is fed to a low pass filter 58. The low pass filter 58 ~~even~~ receives the filtered signal from the rate limit block 34. Before the filtered signal is fed to the low pass filter <u>58</u> the noise level in the signal is estimated in an estimating block 59 and ~~drawn~~ <u>cancelled</u> from the signal. The output signal from the calculation block 42 is an estimation of the effect contents in the EMG signal, which depends on the mentioned probability function.

As shown, the embodiments shown in figures 5 and 6 can be seen as a special case of that shown in figures 7 and 8, where the probability P_{ECG} can assume the value 0 or 1.

The estimated EMG-activity R and the estimated EKG-activity S are transferred to a SN-block 60 for determining a signal-to-noise ratio for each channel between the estimated EMG-activity R and the estimated EKG-activity S. The signal-to-noise ratio can be determined in different ways. One way to determine a signal-to-noise ratio T is ~~through~~ <u>by</u> the quotient

$$T = \frac{R}{R + S}$$

where R is the estimated EMG-activity and S is the estimated EKG-activity.

To promote channels with high estimated EMG-activity (regardless of interferences), it is advantageous to instead use the quotient

$$T = \frac{R^2}{R + S}$$

Instead of R^2, R^n can naturally be used, where n suitably is considerably larger or equal to 1.

The signal-to-noise ratio is transferred to a ~~weight-factor~~ <u>weighting factor</u> block 62, where a weighing is determined for each channel. The determinations in the ~~weight-factor~~ <u>weighting factor</u> block 62 are apparent in Fig. 7. A time block 64 counts time intervals t, for example a few seconds

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long. During the respective time interval t, the maximum signal T1 is determined for the signal-to-noise ratio T from the SN-block 60 in a maximizing block 66. This maximum signal T1 is then filtered in a low pass filter 68. The filtered signal T2 then represents the base for the determination of a ~~weight~~ weighting factor for each channel in a calculation block 70. In this example, the ~~weight~~ weighting factor is set to

$$\frac{T2}{\max T2}$$

where maxT2 is the maximum T2 for all the channels. In other words, the channels are normalized to the strongest signal-to-noise ratio of all the channels, such that the ~~weight~~ weighting factor for the respective channel receives a value between 0 and 1.

The determined ~~weight~~ weighting factors are then transferred to the ~~summator~~ summing unit 36 (Fig. 4), where handling is done as previously described. Finally, the signal can be smoothed in a low pass filter 72 and put out as a ready EMG-signal.

Preferably, a computer program is arranged in the analysis unit 12, which directs the function of the different blocks in the analysis unit according to the above.

In the method according to the present invention, the determination of ~~weight~~ weighting factors for the respective signal channels ~~constitute the main portion~~ plays a major role. ~~Still, it can again be pointed out that the~~ The numerical values given above, e.g. breaking frequencies and multiplication factors, are only ~~given as~~ examples and in no way exclude other values. Similarly, certain portions of the signal handling can be obtained in other ways without deviating from the ~~essence of the~~ invention.

Although modifications and changes may be suggested by those skilled in the art, it is the invention of the inventors to embody within the patent warranted heron all changes and modifications as reasonably and properly come within the scope of their contribution to the art.

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~~Claims~~

WE CLAIM AS OUR INVENTION:

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